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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,743	07/01/2003	Ken Liljegren	05432/000M963US0	7422

7278 7590 03/28/2005

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EXAMINER	
JONES, DWAYNE C	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/619,743	LILJEGREN ET AL.	
	Examiner	Art Unit	
	Dwayne C. Jones	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28JAN2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 8-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-6 and 8-11 are pending.

2. Claims 1-6 and 8-11 are rejected.

Response to Arguments

3. Applicants' arguments filed January 28, 2005 have been fully considered but they are not persuasive. Applicants present the following arguments. Applicants submit the instant claims are neither anticipated nor rendered obvious with the incorporation of the phrase in independent claim 1 regarding the ability "to form a granulate, wherein the granulate after compaction has a median particle size of at least 40 micrometers". However, the fact remains that the instantly filed claims are only directed to a pharmaceutical composition of citalopram, which is defined as a product-by-process claim and is a product, not a process, see In re Bridgeford, 357 F2d 679, 149, USPQ 5 (CCPA 1966). The rest of the claim provides information that is relevant to process of making claims rather than product claims as in the instantly filed application. Furthermore, the incorporation of the phrase in independent claim 1 regarding the ability "to form a granulate, wherein the granulate after compaction has a median particle size of at least 40 micrometers" falls after the phrase "prepared by a process comprising", which is directed to the process steps and not the known composition of citalopram.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3 and 8-11 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bogeso et al. of U.S. Patent No. 4,136,193. This claim is defined as a product-by-process claim and is a product, not a process, see In re Bridgeford, 357 F2d 679, 149, USPQ 5 (CCPA 1966). It is the patentability of the product claimed and not of the recited process steps which must be established, see In re Brown, 459 F2d 531, 173 USPQ 685 (CCPA 1972); In re Wertheim, 541 F2d, 191 USPQ (CCPA 1976). A comparison of the recited process with the prior art processes does not serve to resolve the issue concerning the patentability of the product, see In re Fessman, 489 F2d 742, 180 USPQ 324 (CCPA 1974). Bogeso et al. teach of compounds of citalopram, namely citalopram hydrochloride and citalopram hydrobromide, (see column 2, lines 47-51 and Example 2). Although Bogeso does not specifically recite the process steps, such as using a roller compacting step, the instant claims are anticipated by the prior art of Bogeso et al. because the instant claims are product claims. In addition, the inherent properties of particle sizes of these well known compounds are also anticipated by the prior art of Bogeso et al. because these physical properties, such as particle size, are inherent for the known crystals of citalopram.

Claim Rejections - 35 USC § 103

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-6 and 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bogeso et al. of U.S. Patent No. 4,136,193. Foremost, the instant claims are product claims that contain functional recitations of process steps, which do not patentably distinguish applicants' claims over the prior art. This claim is defined as a product-by-process claim and is a product, not a process, see In re Bridgeford, 357 F2d 679, 149, USPQ 5 (CCPA 1966). It is the patentability of the product claimed and not of the recited process steps which must be established, see In re Brown, 459 F2d 531,

173 USPQ 685 (CCPA 1972); In re Wertheim, 541 F2d, 191 USPQ (CCPA 1976). A comparison of the recited process with the prior art processes does not serve to resolve the issue concerning the patentability of the product, see In re Fessman, 489 F2d 742, 180 USPQ 324 (CCPA 1974). Bogeso et al. teach of compounds of citalopram, namely citalopram hydrochloride and citalopram hydrobromide, (see column 2, lines 47-51 and Example 2). Although Bogeso does not specifically recite the process steps, such as using a roller compacting step, the instant claims are anticipated by the prior art of Bogeso et al. because the instant claims are product claims. In addition, the inherent properties of particle sizes of these well known compounds are also anticipated by the prior art of Bogeso et al. because these physical properties, such as particle size, are inherent for the known crystals of citalopram. Furthermore, the determination of a therapeutic dosage as well as modes and methods of administration is well within the purview of the skilled artisan. Accordingly, it would have been obvious to one having ordinary skill in the art to determine therapeutic dosages that optimize this well-known pharmaceutical agent to a patient.

Obviousness-type Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-6 and 8-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 12, 13, 36, 37, and 41-43 of copending Application No. 09/730,380. Although the conflicting claims are not identical, they are not patentably distinct from each other because both teach of pharmaceutical compositions of citalopram. In addition, the inherent properties of physical properties, such as particle sizes, of these well-known compounds is an inherent feature of these known compounds and obvious to for the skilled artisan to determine because these physical properties, such as particle size, are inherent for the known crystals of citalopram. Furthermore, the determination of a therapeutic dosage as well as modes and methods of administration is well within the purview of the skilled artisan. Accordingly, it would have been obvious to one having ordinary skill in the art to determine therapeutic dosages that optimize this well-known pharmaceutical agent to a patient.

11. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 1-6 and 8-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 64, 65, 67, 69-74, 99-103, and 105-108 of copending Application No. 10/245,824. Although the conflicting claims are not identical, they are not patentably distinct from each other

because both teach of pharmaceutical compositions of citalopram. In addition, the inherent properties of physical properties, such as particle sizes, of these well-known compounds is an inherent feature of these known compounds and obvious to for the skilled artisan to determine because these physical properties, such as particle size, are inherent for the known crystals of citalopram. Furthermore, the determination of a therapeutic dosage as well as modes and methods of administration is well within the purview of the skilled artisan. Accordingly, it would have been obvious to one having ordinary skill in the art to determine therapeutic dosages that optimize this well-known pharmaceutical agent to a patient. In addition, the determination of purity levels is obvious and well within the purview of the skilled artisan.

13. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 1-6 and 8-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10/310,621. Although the conflicting claims are not identical, they are not patentably distinct from each other because both teach of pharmaceutical compositions of citalopram. In addition, the inherent properties of physical properties, such as particle sizes, of these well-known compounds is an inherent feature of these known compounds and obvious to for the skilled artisan to determine because these physical properties, such as particle size, are inherent for the known crystals of citalopram. Furthermore, the determination of a therapeutic dosage as well as modes and methods of administration is well within the purview of the skilled

artisan. Accordingly, it would have been obvious to one having ordinary skill in the art to determine therapeutic dosages that optimize this well-known pharmaceutical agent to a patient.

15. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 1-6 and 8-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 14 of copending Application No. 10/706,886. Although the conflicting claims are not identical, they are not patentably distinct from each other because both teach of pharmaceutical compositions of citalopram. In addition, the inherent properties of physical properties, such as particle sizes, of these well-known compounds is an inherent feature of these known compounds and obvious to for the skilled artisan to determine because these physical properties, such as particle size, are inherent for the known crystals of citalopram. Furthermore, the determination of a therapeutic dosage as well as modes and methods of administration is well within the purview of the skilled artisan. Accordingly, it would have been obvious to one having ordinary skill in the art to determine therapeutic dosages that optimize this well-known pharmaceutical agent to a patient.

17. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. Claims 1-6 and 8-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-20

of copending Application No. 10/741,553. Although the conflicting claims are not identical, they are not patentably distinct from each other because both teach of pharmaceutical compositions of citalopram. In addition, the inherent properties of physical properties, such as particle sizes, of these well-known compounds is an inherent feature of these known compounds and obvious to for the skilled artisan to determine because these physical properties, such as particle size, are inherent for the known crystals of citalopram. Furthermore, the determination of a therapeutic dosage as well as modes and methods of administration is well within the purview of the skilled artisan. Accordingly, it would have been obvious to one having ordinary skill in the art to determine therapeutic dosages that optimize this well-known pharmaceutical agent to a patient.

19. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

20. Claims 1-6 and 8-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-25 and 30-39 of copending Application No. 10/750,049. Although the conflicting claims are not identical, they are not patentably distinct from each other because both teach of pharmaceutical compositions of citalopram. In addition, the inherent properties of physical properties, such as particle sizes, of these well-known compounds is an inherent feature of these known compounds and obvious to for the skilled artisan to determine because these physical properties, such as particle size, are inherent for the known crystals of citalopram. Furthermore, the determination of a therapeutic dosage

as well as modes and methods of administration is well within the purview of the skilled artisan. Accordingly, it would have been obvious to one having ordinary skill in the art to determine therapeutic dosages that optimize this well-known pharmaceutical agent to a patient. In addition, the determination of purity levels is obvious and well within the purview of the skilled artisan.

21. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

22. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-

0578. The examiner can normally be reached on Mondays, Tuesdays, Wednesdays, and Fridays from 8:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, may be reached at (571) 272-0951. The official fax No. for correspondence is (571)-273-8300.

Also, please note that U.S. patents and U.S. patent application publications are no longer supplied with Office actions. Accordingly, the cited U.S. patents and patent application publications are available for download via the Office's PAIR, see http://pair-direct.uspto.gov. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 1-866-217-9197 (toll free).

DWAYNE JONES
PRIMARY EXAMINER
Tech. Ctr. 1614
March 21, 2005